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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,475	10/10/2001	Ryuichi Morishita	6235-59221	4309

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EXAMINER
WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,475	Applicant(s) MORISHITA ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10 October 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: 10 .

DETAILED ACTION

Non-Final Rejection

Claims 1-21 are pending examination.

Election/Restrictions

Applicants elected the species lower limb diabetic ischemic disease with traverse in paper no. 9. Applicants' traverse the restriction for the election of species for the following reason: The international search authority found unity of invention as evidenced by the ISR (Exhibit A); the pending claims are all directed to the treatment of diabetic ischemic and the location of the ischemic is not sufficient to warrant separation into species. See pages 1-2 and Exhibit A.

Applicants' traversal is acknowledged and is not found persuasive for the following reasons: the species listed in claims 3, 11, and 18 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special features for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (e), the inventions listed as species in claims 3, 11, and 18 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth in paper no. 8. In view of 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), a therapeutic agent comprising a nucleic acid encoding HGF is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

Furthermore, the technical feature of species appears to be that they all relate to a therapeutic comprising a nucleic acid encoding HGF. However, Aoki et al. (IDS, Circulation, Vol. 98, 1998, 1321, abstract 1682) teaches a transfection method comprising the claimed product (HVJ liposome and HGF).

Therefore, the technical feature linking the species does not constitute a special technical feature as defined by PCT 13.2, as it does not define a contribution over the prior art.

As the technical feature linking the members of the listed in claim does not constitute a special feature as defined by PCT Rule 13.2, particularly since each disease listed in the claims do not share a structural feature in common with respect to their site of action. More specifically, treating diabetes lower limb ischemic would not result in treatment of diabetic ischemic myocardial infarction and would require a different route of administration would be required for each different type of diabetic ischemic disease. Thus, the requirement of unity of the invention is not fulfilled.

As set forth above and in paper no. 8 the examiner followed the guidelines under PCT Rule 13.1 and 13.2 provided by the MPEP and under the guidelines the restriction is deemed

proper. In addition, other than asserting that the international examiner did not consider a lack of unity and the pending claims are all directed to the treatment of diabetic ischemic and the location of the ischemic is not sufficient to warrant separation into species, the applicant has not provided sufficient guidance to overcome the lack of unity.

Thus, the examiner followed the PCT lack of unity guidelines provided by the MPEP.

The restriction is deemed proper and is made **Final**.

The species not elected from claims 3, 11, 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Priority

Acknowledgement is made to PCT/JP00/07502 filed on 10/16/00 and foreign priority to Japanese Application No. 11/309984 filed on 10/29/99.

Specification

The attempt to incorporate subject matter into this application by reference to PCT/JP00/07502 is improper because the specification is lacking in the first sentence of the specification whether the international application was published under PCT Article 21(2) in English. See MPEP 202.01 and 37 CFR 1.78.

Claim Objections

Claims 1 and 9 are objected to because of the following informalities: The pre-amble of claims 1 and 9 are grammatically incorrect and should read "A method for the treatment of a diabetic ischemic disease in a subject". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Note: In view of the 112 2nd rejection of claims 17-21 because of the phrase "Use of a nucleic acid encoding HGF", the claims read on either "a product" or "a method". If the claims read on a method, the following rejection under 112 first apply.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) A therapeutic agent for reducing a diabetic ischemic disease in a subject, comprising a therapeutically effective amount of a nucleic acid encoding hepatocyte growth factor (HGF) protein; 2) A method for reducing a diabetic ischemic disease in a subject, comprising directly administering the agent of 1 to an ischemic site in a subject having a diabetic ischemic disease, thereby increasing angiogenesis at said ischemic site, and does not reasonably provide enablement for the full scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence

or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants are reminded that intended use such as claims 1-8 have patentable weight for enablement, while intended use have little or no relevant weight for art purposes. Claims 1-8 are examined here for the phrase: "for use for treating a diabetic ischemic disease in a subject".

The claimed invention is directed to a method of gene therapy for treating diabetic ischemic disease in a subject comprising administering a DNA encoding a hepatocyte growth factor to the subject. The claimed invention further contemplates administering the DNA with a liposome. In addition, the as-filed specification states, "it is know that angiogenesis hardly occurs and prognosis is unfavorable in ischemic disease complicated with or caused by diabetes and at present it is not known whether HGF gene administration to such diabetic ischemic disease is effective or not (pages 2-3). The field of the invention lies in gene therapy.

Furthermore, and with respect to claims directed to any vector useful for gene therapy and directed to any treatment of a mammal; the state of the art in 1998, exemplified Anderson et al., *Nature*, Vol. 392, pp. 25-30, April 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

1) The type of vector and amount of DNA constructs to be administered,

2) The route and time course of administration, the sites of administration, and successful uptake of the claimed DNA at the target site;

3) The trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA product, the amount and stability of the protein produced, and

4) What amount of the expressed proteins considered to be therapeutically effective for a DNA therapy method (Anderson, *Nature*, Vol. 392, pp. 25-30, April 1998).

In addition, all of these issues differ dramatically based on the specific vector used, the route of administration, the animal being treated, therapeutically effective amount of the DNA, and the disease being treated.

Anderson teaches that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact on the treatment of disease, and that several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (pp. 25-30).

Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack the basis understanding of how vectors should be constructed what regulatory sequences are appropriated for which cell types (page 30, column 1, last paragraph). Furthermore, Verma, (IDS, *Nature*, Vol. 389, pages 239-242, 1997), indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). Therefore, at the time the application was filed gene therapy was considered unpredictable.

The specification provides working examples that will be described briefly herein:

The inventors observed that direct administration of the HGF gene to the ischemic site revealed effective results (page 2). On page 10 and pages 11-12, the disclosure teaches production of an agent comprising HVJ liposome containing HGF gene and injection of the

agent to the lower limb skeletal muscle of a diabetic rat (diabetes was provoked by interperitoneal administration of streptozotocin ischemic limb skeletal muscle) and control rats (ischemic rat of normal rat). Reference 1 measured the perfusion 3 and 5 weeks after administration of the agent to rats (page 11). The internal HGF concentration in the muscles was significantly lower in muscles of the ischemic site of the diabetic rat than the control rat. Therefore, angiogenesis hardly occurs in diabetic lower limb ischemic rat and bypass circulation did not develop (Figure 2). Reference 3 teaches an in vitro experiment displaying angioendothelial cells under high glucose concentration show a decrease in MMP-1 expression, which is a matrix-cleaving enzyme essential for angiogenesis, and show a decrease in the expression of mRNA of the transcription factor ETS-1, which is expressed and increases during angiogenesis. Reference 3 further teaches that when HGF is added to the cells under high glucose conditions, MMP-1 expression and mRNA of ETS-1 expression increase significantly. Thus, HGF makes angiogenesis easier.

With respect to treating a method for the treatment of a diabetic ischemic disease, the claimed invention is only enabled for reducing diabetic ischemic disease and not for the full scope of the claimed invention because the breadth of the term "treatment" encompasses complete regression or recovery and/or protection from said disease. The state of the art teaches that there is no optimal medical therapy for critical limb ischemia (Taniyama et al., Circulation, Vol. 104:2344-2350, 2001). The as-filed specification lacks sufficient guidance for how reducing perfusion in the lower limb of an experimental rat (rat diabetic hind-limb model) reasonably correlates to treating (complete regression or recovery from the disease) a mammal having diabetes ischemia disease. The state of the art teaches that for gene therapy to be useful

in human, the animal vascular injury and human percutaneous coronary intervention must produce similar physical insult to the vascular wall and provoke a similar injury response. Unfortunately, we cannot be certain that this is the case (O'Sullivan et al. Heart, 2001, pages 1-5). Furthermore, since the breadth of the term "treatment" encompasses preventing diabetes ischemia disease in a mammal, the as-filed specification and the state of the art fail to provide sufficient guidance for one skilled in the art to reasonably determine what mammals are susceptible to diabetes ischemia. In addition, in view of the transient nature of gene expression, it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from reducing the disease in a mammal that has diabetes ischemia to treating a mammal that is susceptible to the disease. Thus, the as-filed specification fails to provide sufficient guidance for one skilled in the art to use a composition comprising HGF gene product for preventing diabetes ischemia disease in a mammal susceptible to the disease. Therefore, in view of the In Re Wands factors, the claimed invention is only enabled for reducing diabetes ischemia disease and the full scope of the claims.

In addition, the as-filed specification provides sufficient guidance for one skilled in the art to make and/or use a vector comprising a HGF gene product for reducing diabetic ischemic disease in a subject comprising direct administration of the vector to the ischemic site. However, the as-filed specification fails to provide sufficient guidance for one skilled in the art to make and/or use the full scope of the claimed invention comprising using any route of administration other than direct to reduce diabetic ischemic disease in a subject because of the unpredictability of gene therapy. In view of the concerns set forth above for using any route of administration other than direct administration, the concerns set forth by Anderson and Verma are further

supported by Das et al. (IDS, Ann Thorac Surg, Vol. 68, pg. 1929, 1999), Kim et al. (Arch. Pharm. Res., Vol. 24, pp. 1-15, 2001), and Mulligan (IDS, Science, Vol. 260, 1993). More specifically, Kim further confirms the doubts expressed by Anderson and Verma about the unpredictability of gene therapy. Kim teaches several problems with gene therapy, which are 1) route of administration; 2) the barriers the gene encounters after administration; 3) advantages and disadvantages of different types of vectors; 4) expression system (pages 1-10). Therefore, it would take an undue amount of experimentation to reasonably extrapolate from directly administering the agent comprising a HGF gene to using any other route for administration of the agent because of the art of record teaching the unpredictability of gene therapy and the lack of guidance provided by the as-filed specification for using any route of administration other than direct administration.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, which of the claimed therapeutic agent generates a therapeutic effect, how is it apparent as to how one skilled in the art, without any undue experimentation, practices any nucleic acid therapy method as contemplated by the claims, particularly given the unpredictability of nucleic acid therapy as a whole and/or the doubts expressed in the art of record.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable the for 1-2 listed above. Given that gene therapy wherein any carrier is employed to correct a disease or a medical condition in any mammal was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to a gene therapy effect

produced by any gene delivery vector cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the full scope of the claimed invention based on the applicant's disclosure and the unpredictability of gene therapy.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the subject" in page 3 of the amendment. There is insufficient antecedent basis for this limitation in the claim. In the art of therapy there are many subjects (human, monkey, dog, snake, etc.) and the claim does not particularly point out and distinctly claim which subject is being referred to. In addition, the independent claim, which, claim 16 depends on does not claim "a subject".

Claims 17-21 provide for the use of a nucleic acid encoding HGF, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is not apparent whether the claims are directed to a method or a product. Clarification is requested.

Claims 17-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 26-28 of co-pending Application No. 09/857,719 although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application uses the same composition claimed in co-pending application, each composition comprises a nucleic acid encoding hepatocyte growth factor (HGF) or further comprising a HVJ-liposome.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of co-pending Application No. 09/986,374 although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application uses the same composition

claimed in co-pending application, each composition comprises a nucleic acid encoding hepatocyte growth factor (HGF) or further comprising a HVJ-liposome.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-8 are directed to a therapeutic agent for treating a diabetic ischemic disease in a subject. The intended use of a product, in the instant claims for the therapeutic agent, does not have patentable weight for prior art rejections. An intended use does not provide an alteration to the therapeutic agent that distinguishes it from that taught in the art of record.

Claims 1-7 and 17-20 as a product are rejected under 35 U.S.C. 102(e) as being anticipated by Morishita et al. (US Patent No. 6,248,722). Morishita teaches an expression

vector containing a HGF gene in a therapeutically effective amount (column 14, claims 1-6). Morishita further teaches either a non-viral or viral expression vector containing the HGF gene, wherein said non-viral vector is encapsulated in a liposome, the membrane of which may be further fused to attenuated Sendai virus particles (column 14, claims 2, 4, and 6).

Claims 1-5, 7, 9-10, and 17-19 as a product, are rejected under 35 U.S.C. 102(e) as being anticipated by Isner et al. (IDS, US Patent No. 5,562,225). Isner teaches a first DNA encoding an angiogenic protein selected from hepatocyte growth factor (HGF) having an operably linked secretory signal sequence (columns 21-22, claim 1).

Claims 1-7 and 17-21 as a product are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki et al. (IDS, Circulation, Vol. 98, 1998, 1321, abstract 1682). Aoki teaches a composition comprising HVJ liposome and HGF.

Claims 1-5, 7-12, 15-19, and 21 as a product are rejected under 35 U.S.C. 102(b) as being anticipated by Van Belle et al. (IDS, Circulation, Vol. 97, pp. 381-390, 1998). Van Belle teaches a product comprising HGF (page 383).

Claims 1-5, 7, and 17-19 as a product are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (IDS, WO 99/36103). Miller teaches HGF expression vectors (pages 12-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over co-pending Application No. 09/857,719 (The assignee of this application is not apparent), which has two common inventors (Morishita and Ogihara) with the instant application. Based upon the earlier effective U.S. filing date of the co-pending application, it would constitute prior art under

35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Morishita teaches a composition comprising HGF, which may be fused to attenuated Sendai virus particles.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the co-pending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the co-pending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-8 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over co-pending Application No. 09/029,497 (The assignee of this application is not apparent), which has two common inventors (Morishita and Ogihara) with the instant application. Based upon the earlier effective U.S. filing date of the co-pending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Morishita teaches a composition comprising HGF, which may be fused to attenuated Sendai virus particles.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the co-pending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the co-pending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Brian Whiteman
Patent Examiner, Group 1635
9/27/02

DAVE T. NGUYEN
PRIMARY EXAMINER